REMARKS

I. Status of the Claims

In response to a restriction requirement, applicants elected to prosecute claims 9 and 22, *i.e.*, the Group V claims. Thus, in light of linking claims, claims 1-9, 12 and 17-24 are under consideration, and the remaining claims stand withdrawn. The examined claims are rejected under 35 U.S.C. §112, first and second paragraphs, and 35 U.S.C. §103, and oath & declaration, the specification and the claims are objected to. The specific grounds for rejection/objection are set out in detail below.

II. Objections

A. Oath & Declaration

The examiner has objected to the oath & declaration. A new oath is provided herewith.

B. Specification

The examiner has objected to the specification due to the inclusion of trademarks. An amendment is provided that addresses the examiner's concerns. Other clarifying amendments also are provided.

C. Claims

Claims 9 and 22 are objected to as containing non-elected subject matter. Claim 22 is canceled. Because claim 9 links various other species eligible for rejoinder, it is requested that the objection be held in abeyance.

III. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-9, 12 and 17-24 are rejected as indefinite. The rejection of claim 1 is believed to be addressed by amendments provided above, support for which can be found, for example, at pages 17 and 19, Example 1, and in pending claim 26. The rejection of claim 21 is moot given that it has been canceled. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

IV. Rejections Under 35 U.S.C. §112, First Paragraph

A. Written Description

Claims 1-9, 12 and 17-24 are rejected as lacking an adequate written description. According to the examiner, the claims exceed the scope of written support in (a) encompassing treatment of non-human subjects, (b) recite use of a diverse genus of human immunoglobulins that bind human EpCAM, (c) recite use of antibodies with potentially infinite half-lives, (d) encompassing treatment of non-malignant diseases. Applicants traverse, but in the interest of advancing the prosecution, the claims have been amended to address each of the issues presented above. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Enablement

Claims 1-9, 12 and 17-24 are rejected as lacking an enabling disclosure. In general, the issues set forth here are the same as those raised above with respect to written description. Therefore, it is believe that the previously discussed amendments address the enablement issues as well. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. Rejection Under 35 U.S.C. §103

Claims 1-9, 12 and 17-24 are rejected as obvious over Kufer *et al.* in view of Raum *et al.*, and Naundorf *et al.*, as evidenced by Oberneder *et al.*, Loh *et al.*, and Leyland-Jones. Applicants traverse.

SEQ ID NOS: 1 and 2 indeed correspond to MT201 sequences. However, even if one were to consider the half-life of the antibody to be an inherent feature, the primary references (Kufer *et al.*, Raum *et al.*, Naundorf *et al.*) fail to teach or suggest the claimed specific regimen according to which the specific antibody referred to in claim 1 is administered to tumor patients - no more frequently than once every two weeks. The human anti-EpCAM immunoglobulin comprising SEQ ID NOS: 1 and 2 has a serum half-life of 15-20 days (see Specification at page 19, second paragraph). This relatively long serum half-life implies that the anti-EpCAM immunoglobulin administered as part of the claimed method will not be cleared from the blood as rapidly as another immunoglobulin with a shorter half-life, for example, that of ING-1 as discussed in the present application.

The recited dosing frequency according to claim 1 corresponds approximately to the half-life of the immunoglobulin. As such, the serum level of this immunoglobulin in the interim between two consecutive administrations will never have decreased by more than about one-half its amount immediately following the respective previous administration. This means that the dosage of any given administration need be no higher than the amount required to lead, immediately after administration, to approximately two times the predetermined serum trough level reached by the time of the next administration.

Why is this significant? The enhanced persistence in the serum allows less of the anti-EpCAM immunoglobulin to be administered at one time than would be possible for another anti-EpCAM of shorter serum half-life while still maintaining a certain predetermined serum trough level, *i.e.*, while ensuring that the total serum concentration of therapeutic agent never drops below the minimum level determined to be necessary for continued efficacy between two consecutive administrations. This has the advantageous effect that less of the anti-EpCAM immunoglobulin of the method of the invention needs be applied in any given dose, thereby eliminating the possibility of, or at least mitigating, any adverse and/or toxic side effects. In addition, the relatively long half-life of the anti-EpCAM immunoglobulin as used in the method of the invention also implies that administration need not take place too frequently, thereby increasing the quality of life for the patient and reducing total cost of therapy. And of course, the long half-life of the immunoglobulin provides the benefit of one or both of ADCC and CDC for a longer period of time, and at higher levels than possible using an anti-EpCAM immunoglobulin with a shorter half-life.

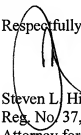
Finally, with respect to the examiner's argument that it would have been obvious to one ordinarily skilled in the art to have determined the most appropriate doses, schedules and routes of administration for an antibody therapy, such an argument is both unsupported and untrue. In point of fact, more than 200 patients with different kind of tumors had to be tested with the claimed human anti-EpCAM immunoglobulin in clinical trials in order to arrive at the now claimed optimal regimen. Thus, there is no evidence, no reason to believe, that it was simply "obvious" as argued by the examiner.

In sum, the claims as presented for reconsideration describe methodologic aspects that were neither taught nor suggested by the cited art. As such, no *prima facie* case exists. Reconsideration and withdrawal of the rejection is therefore requested.

VI. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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